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## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE	) ) )
LITIGATION	) MDL NO. 1456
	) Civil Action No. 01-12257-PBS
	) Judge Patti B. Saris
THIS DOCUMENT RELATES TO:	) -
	) Chief Magistrate Judge Marianne B
	) Bowler
State of Montana v. Abbott Labs., Inc., et al.,	)
CA No. 02-CV-12084-PBS	)

## DECLARATION OF GERALD ROSENBERG IN SUPPORT OF BAYER CORPORATION'S MOTION FOR SUMMARY JUDGMENT

- I, Gerald Rosenberg, hereby declare and state as follows:
- 1. I am over the age of 21 and am competent to testify regarding the matters set forth in this declaration. I currently serve as Senior Vice President Executive Development for Bayer HealthCare, a position I have held since June 2004. From 1987 to 1995, I served as Senior Vice President of Marketing and Sales for Bayer's Pharmaceutical Division. From 1995 to 2001, I served as Senior Vice President and General Manager of the Pharmaceutical Division. From January 2001 to June 2004, I was General Manager of Diagnostics for the North American Region. I have acquired personal knowledge of the facts stated below while serving in these positions.
- 2. From 1987 to 2001, I was integrally involved in Bayer's decision-making concerning pharmaceutical product pricing. I have been involved, in particular, in the pricing decisions related to Cipro, Cipro IV, DTIC-Dome, and Mithracin. I do not address the other Bayer products at issue in this case Koate, Kogenate, and Gamimune because those are

biologic products that were within the purview of Bayer's Biologics Division, rather than the Pharmaceutical Division.

- 3. Cipro was the brand name under which Bayer marketed drugs for oral administration containing the active ingredient Ciprofloxacin, a synthetic broad spectrum antimicrobial used to treat various infections. Bayer sold Cipro in tablet form with 250 mg, 500 mg, and 750 mg strengths in 50- or 100-tablet bottles, or in 100 Unit Dose blister packs. Bayer sold Cipro in a 100-mg tablet in a "Cystitis" pack of 6 tablets. Bayer also supplied Cipro as an oral suspension in 100 mL bottles of two strengths, 5% (5g in 100 mL) and 10% (10g in 100 mL).
- 4. Cipro IV was the brand name under which Bayer marketed Ciprofloxacin for intravenous administration. Bayer made Cipro IV available in 200 mg, 400 mg, and 1200 mg strengths in 20 mL, 40 mL, and 120 mL vials, respectively. Prior to administration, the concentrate in these vials had to be diluted with a suitable intravenous solution. Bayer also sold Cipro IV in premixed 100 mL and 200 mL flexible bags, which did not need to be diluted before administration.
- 5. In 2002, Bayer introduced Cipro XR, an extended release tablet for oral administration containing two forms of Ciprofloxacin. Cipro XR is used in the treatment of certain urinary tract infections.
- 6. On October 1, 2004, Bayer transferred responsibility for commercialization of a number of its primary care pharmaceutical products, including Cipro, Cipro IV, and Cipro XR, to Schering Plough. As of January 1, 2005, Bayer no longer sold any Cipro or Cipro XR products.

  As of September 1, 2005, Bayer no longer sold any Cipro IV products.

- 7. DTIC-Dome was the brand name under which Bayer marketed the drug dacarbazine. It was used to treat skin cancer and, in combination with other drugs, as a secondary-line therapy for patients suffering from Hodgkin's disease. DTIC-Dome was administered intravenously, and, in the overwhelming number of cases, in a hospital setting.
- 8. Dacarbazine is a multisource drug. Competing manufacturers of dacarbazine include Abraxis Pharmaceutical Products, Bedford Laboratories, Mayne Pharmaceuticals, and Sicor Pharmaceuticals.
- 9. Because newer therapies came on the market that nearly eliminated the demand for DTIC-Dome, Bayer has not actively promoted or marketed DTIC-Dome for at least the last 20 years. During that time, Bayer did not maintain any dedicated sales force for DTIC-Dome, nor did it provide its other sales representatives any targets or incentives for DTIC-Dome sales. Bayer discontinued selling DTIC-Dome all together in 2006. Consistent with very low demand for DTIC-Dome in general, Bayer's records reflect that the State of Montana reimbursed providers for less than \$2500 worth of DTIC-Dome since 1990 and that it made no payments for DTIC-Dome after 1999.
- 10. Mithracin was the brand name under which Bayer marketed the drug plicamycin. Mithracin was used to treat carefully selected hospitalized patients with malignant tumors of the testis in whom successful treatment by surgery and/or radiation was unlikely. Mithracin was administered intravenously and almost exclusively in a hospital setting.
- 11. Because newer therapies came on the market that nearly eliminated the demand for Mithracin, Bayer has not actively promoted or marketed Mithracin for at least the past 20 years. During that time period, as with DTIC-Dome, Bayer did not maintain any dedicated sales

force for Mithracin, nor did it provide its other sales representatives any targets or incentives for Mithracin sales. Bayer discontinued selling Mithracin all together in 2001.

- Mithracin, it established the drugs' "Wholesale Price" ("WP"). Bayer's WP is its equivalent of other manufacturers' so-called "Wholesale Acquisition Cost" ("WAC"). Bayer sells the vast majority of its pharmaceutical products to wholesalers who pay WP, including the vast majority of Cipro, Cipro IV, Cipro XR, DTIC-Dome, and Mithracin. Because WP is a price wholesalers actually pay for Bayer drugs, Bayer periodically adjusts its WP to reflect changing market conditions.
- 13. Bayer reviewed and, if necessary, revised the WP for its pharmaceuticals each year. Bayer would change its WP based on the following factors: (1) competitors' price changes, both on an individual tablet and course-of-therapy basis; (2) unique features or therapeutic advantages of Bayer's drugs; (3) any new indications for the Bayer drug; and (4) any other lifecycle events for the drug.
- 14. In addition to WP, Bayer's pharmaceutical products have also had an "Average Wholesale Price" ("AWP"). AWP is a reference price determined formulaically based on a drug's WP. Through 2001, and thus throughout the time period relevant in this case, all of Bayer's pharmaceutical products including Cipro, Cipro IV, DTIC-Dome, and Mithracin had an AWP equal to WP times 1.20. Put another way, AWP was 20% higher than WP, and WP was 16.7% lower than AWP.

15. As Bayer adjusted its WPs to reflect market conditions, its AWPs adjusted accordingly so that the two prices maintained their constant formulaic relationship — AWP at 20% above WP, WP at 16.7% below AWP. For this reason, Bayer was known in the industry as a "16.7% house."

I declare under the penalty of perjury that the foregoing is true and correct.

Dated: February 6, 2007

Gerald Rosenberg